

EXHIBIT 16

The active ingredients in the majority of our current Specialty Generics products and products in development, including oxycodone, oxymorphone, morphine, fentanyl and hydrocodone, are listed by the DEA as Schedule II or III substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation and the DEA limits both the availability of these active ingredients and the production of these products. As discussed in "Regulatory Matters" within this Item 1. Business, we must annually apply to the DEA for procurement and production quotas in order to obtain and produce these substances. The DEA has complete discretion to adjust these quotas from time to time during the calendar year and, as a result, our procurement and production quotas may not be sufficient to meet commercial demand or to conduct bioequivalence studies and clinical trials. Any delay or refusal by the DEA in granting, in whole or in part, our quota requests for controlled substances could delay or result in the stoppage of the manufacture of our pharmaceutical products, our clinical trials or product launches and could require us to allocate product among our customers.

Sales, Marketing and Customers

Sales and Marketing

We market our branded products to physicians (including neurologists, rheumatologists, nephrologists, pulmonologists, ophthalmologists, neonatologists and surgeons), pharmacists, pharmacy buyers, hospital procurement departments, ambulatory surgical centers, and specialty pharmacies. We distribute our branded and generic products through independent channels, including wholesale drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, hospital networks, ambulatory surgical centers and governmental agencies. In addition, we contract with GPOs and managed care organizations to improve access to our products. We sell and distribute API directly or through distributors to other pharmaceutical companies.

For further information on our sales and marketing strategies, refer to "Our Businesses and Product Strategies" included within this Item 1. Business.

Customers

Net sales to distributors that accounted for more than 10% of our total net sales in fiscal 2017, 2016, 2015 and the three months ended December 30, 2016 were as follows:

	Fiscal Year Ended			Three Months Ended
	December 29, 2017	December 30, 2016	December 25, 2015	December 30, 2016
CuraScript, Inc.	40%	38%	35%	43%
McKesson Corporation	*	12%	20%	10%
AmerisourceBergen Corporation	*	*	10%	*
Cardinal Health, Inc.	*	*	11%	*

* - Net sales to these distributors were less than 10% of our total net sales during the respective periods presented above.

No other customer accounted for 10% or more of our net sales in the above periods presented.

Manufacturing and Distribution

As of December 29, 2017, we had nine manufacturing sites, including seven located in the U.S., as well as sites in Canada and Ireland, which handle production, assembly, quality assurance testing, packaging and sterilization of products for our Specialty Brands and Specialty Generics segments. Approximately, 93% and 7% of our manufacturing production (as measured by cost of production) was performed within the U.S. and Canada, respectively, in fiscal 2017.

As of December 29, 2017, we maintained distribution centers in 9 countries. In addition, in certain countries outside the U.S. we utilize third-party distribution centers. Products generally are delivered to these distribution centers from our manufacturing facilities and then subsequently delivered to the customer. In some instances, product is delivered directly from our manufacturing facility to the customer. We contract with a wide range of transport providers to deliver our products by road, rail, sea and air.

We utilize contract manufacturing organizations ("CMOs") to manufacture certain of our finished goods that are available for resale. We most frequently utilize CMOs in the manufacture of our Specialty Brands products, including H.P. Acthar Gel (for finish and filling of the product), Ofirmev, Recothrom and Therakos products.

material adverse consequences for the pharmaceutical industry as a whole and, consequently, also for us. However, we believe we have provided for our best estimate of potential refunds based on current information available.

From time to time, legislative changes are made to government healthcare programs that impact our business. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 created a new prescription drug coverage program for people with Medicare through a new system of private market drug benefit plans. This law provides a prescription drug benefit to seniors and individuals with disabilities in the Medicare program ("Medicare Part D"). Congress continues to examine various Medicare policy proposals that may result in pressure on the prices of prescription drugs in the Medicare program.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, "the Healthcare Reform Act") provided for major changes to the U.S. healthcare system, which impacted the delivery and payment for healthcare services in the U.S. Several provisions of the Healthcare Reform Act have already taken effect, including the elimination of lifetime caps and no rescission of policies or denial of coverage due to preexisting conditions, improving patients' ability to obtain and maintain health insurance. Our business has been most notably impacted by rebates from the Medicaid Fee-For-Service Program and Medicaid Managed Care plans and the imposition of an annual fee on branded prescription pharmaceutical manufacturers. Medicaid provisions reduced net sales by \$94.4 million, \$82.3 million and \$43.5 million in fiscal 2016, 2015, and 2014, respectively. The fiscal 2016 increase in provisions for Medicaid payments is primarily attributable to a \$16.9 million increase associated with Acthar, due to double-digit net sales growth, which was partially offset by lower net sales of Specialty Generics. The fiscal 2015 increase in provisions for Medicaid payments is primarily attributable to a \$41.7 million increase associated with Acthar, as fiscal 2015 included a full year of results for the product, which was partially offset by lower net sales of Methylphenidate ER. The Company was also impacted by the annual fee on branded prescription pharmaceutical manufacturers, which is not tax deductible, and recorded expense of \$23.3 million, \$20.0 million and \$0.9 million in fiscal 2016, 2015, and 2014, respectively, within selling, general and administrative expenses. The fee significantly increased in fiscal 2015 due to the inclusion of a full year of results associated with Acthar. We expect this branded pharmaceutical fee and Medicaid provisions to increase in future periods at rates that are consistent with net sales growth. There are a number of other provisions in the legislation that collectively are expected to have an immaterial impact to the Company.

Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the U.S., there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations, including the U.S. Anti-Kickback Statute and similar state statutes, the False Claims Act and the Health Insurance Portability and Accountability Act of 1996. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws apply to hospitals, physicians and other potential purchasers of our products and are potentially applicable to us as both a manufacturer and a supplier of products reimbursed by federal healthcare programs. In addition, some states in the U.S. have enacted compliance and reporting requirements aimed at drug manufacturers.

We are also subject to the Foreign Corrupt Practices Act of 1977 and similar worldwide anti-bribery laws in non-U.S. jurisdictions, such as the United Kingdom ("U.K.") Bribery Act of 2010, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws; however, we operate in many parts of the world that have experienced governmental corruption to some degree and, in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents.

Compliance Programs

In order to systematically and comprehensively mitigate the risks of non-compliance with regulatory requirements described within this Item 1. Business, we have developed what we believe to be a robust compliance program based on the April 2003 Office of the Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers, the U.S. Federal Sentencing Guidelines, the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, the Code of Ethics of the Advanced Medical Technology Association, the U.K. Anti-Bribery guidance, and other relevant guidance from government and national or regional industry codes of behavior. We conduct ongoing compliance training programs for all employees and maintain a 24-hour ethics and compliance reporting hotline with a strict policy of non-retaliation. Our compliance programs are facilitated by our Chief Compliance Officer, who reports directly to the Chief Executive Officer and the Compliance Committee of our Board of Directors. The Compliance function is independent of the manufacturing and commercial operations functions and is responsible for implementing our compliance programs.

As part of our compliance program, we have implemented internal cross-functional processes to review and approve product-specific promotional materials, presentations and external communications to address the risk of misbranding or mislabeling our products through our promotional efforts. In addition, we have established programs to monitor promotional speaker activities and field sales representatives, which includes a "ride along" program for field sales representatives similar to those included in recent Corporate Integrity Agreements from the OIG in order to obtain first-hand observations of how approved promotional and other materials are used, as well as monitoring of sales representative expenses. We have also implemented a comprehensive controlled substances compliance program, including anti-diversion efforts and we regularly assist federal, state and local law enforcement and prosecutors in the U.S. by providing information and testimony on our products and placebos for use by the DEA and other law enforcement agencies in investigations and at trial. As part of this program, we also work with some of our customers to help develop and implement what we believe are best practices for SOM and other anti-diversion activities.

We believe our compliance program design also addresses our FDA, healthcare anti-kickback, anti-fraud, and anti-bribery-related risks. We believe we have complied with reporting obligations of the U.S. Federal Physician Payment Sunshine Act and relevant state disclosure laws and have implemented a program across the Company to track and report data per Centers for Medicare and Medicaid Services ("CMS") guidance and state disclosure requirements.

Outside the United States

Outside the U.S., we must comply with laws, guidelines and standards promulgated by other regulatory authorities that regulate the development, testing, manufacturing, marketing and selling of pharmaceuticals, including, but not limited to, Health Canada, the Medicines and Healthcare Products Regulatory Agency in the U.K., the Irish Medicines Board, the European Medicines Agency and member states of the E.U., the State Food and Drug Administration in China, the Therapeutic Goods Administration in Australia, the New Zealand Medicines and Medical Devices Safety Authority, the Ministry of Health and Welfare in Japan, the European Pharmacopoeia of the Council of Europe and the International Conference on Harmonization. Although international harmonization efforts continue, many laws, guidelines and standards differ by region or country.

We currently market our products in Canada, in various countries in the E.U., and in the Latin American, Middle Eastern, African and Asia-Pacific regions. The approval requirements and process vary by country, and the time required to obtain marketing authorization may vary from that required for FDA approval. Certain drug products and variations in drug product lines also must meet country-specific and other local regulatory requirements. The following discussion highlights some of the differences in the approval process in other regions or countries outside the U.S.

European Union. Marketing authorizations are obtained pursuant to either a centralized or decentralized procedure. The centralized procedure, which provides for a single marketing authorization valid for all E.U. member states, is mandatory for the approval of certain drug products and is optional for novel drug products that are in the interest of patient health. Under the centralized procedure, a single marketing authorization application is submitted for review to the European Medicines Agency, which makes a recommendation on the application to the European Commission, who determines whether or not to approve the application. The decentralized procedure provides for concurrent mutual recognition of national approval decisions, and is available for products that are not subject to the centralized procedure.

The E.U. has also adopted directives and other laws that govern the labeling, marketing, advertising, supply, distribution and drug safety monitoring and reporting of drug products. Such directives set regulatory standards throughout the E.U. and permit member states to supplement such standards with additional requirements.

European governments also regulate drug prices through the control of national healthcare systems that fund a large part of such costs to patients. Many regulate the pricing of a new drug product at launch through direct price controls or reference pricing and, recently, some have also imposed additional cost-containment measures on drug products. Such differences in national pricing regimes may create price differentials between E.U. member states. Many European governments also advocate generic substitution by requiring or permitting prescribers or pharmacists to substitute a different company's generic version of a brand drug product that was prescribed, and patients are unlikely to take a drug product that is not reimbursed by their government.

Emerging Markets. Many emerging markets continue to evolve their regulatory review and oversight processes. At present, such countries typically require prior regulatory approval or marketing authorization from large, developed markets (such as the U.S.) before they will initiate or complete their review. Some countries also require the applicant to conduct local clinical trials as a condition of marketing authorization. Many emerging markets continue to implement measures to control drug product prices, such as implementing direct price controls or advocating the prescribing and use of generic drugs.

immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

The FDA also conducts periodic inspections of drug and device facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could materially adversely affect our business, results of operations, financial condition and cash flows. Additionally, imported API and other components needed to manufacture products could be rejected by U.S. Customs and Border Protection, usually after conferring with the FDA. In the case of domestic facilities, the FDA could initiate product seizures or, in some instances, require product recalls and seek to enjoin a product's manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an "unacceptable supplier," thereby disqualifying that company from selling products to federal agencies.

United States

In general, drug manufacturers operate in a highly regulated environment. In the U.S., we must comply with laws, regulations, guidance documents and standards promulgated by the FDA, the Department of Health and Human Services ("DHHS"), the DEA, the Environmental Protection Agency ("EPA"), the Customs Service and state boards of pharmacy.

The FDA's authority to regulate the safety and efficacy of pharmaceuticals comes from the FFDCA. In addition to reviewing NDAs, for branded drugs, and ANDAs, for generic drugs, the FDA has the authority to ensure that pharmaceutical products introduced into interstate commerce are neither "adulterated" or "misbranded." Adulterated means that the product may cause or has caused injury to patients when used as intended because it fails to comply with cGMP. Misbranded means that the labels of, or promotional materials for, the product contain false or misleading information. Failure to comply with applicable FDA and other federal and state regulations could result in product recalls or seizures, partial or complete suspension of manufacturing or distribution, refusal to approve pending NDAs or ANDAs, monetary fines, civil penalties or criminal prosecution.

In order to market and sell a new prescription drug product in the U.S., a drug manufacturer must file with the FDA a NDA that shows the safety and effectiveness of (a) a new chemical entity that serves as the API, known as a 505(b)(1) NDA; or (b) a product that has significant differences from an already approved one, known as a 505(b)(2) NDA. Alternatively, in order to market and sell a generic version of an already approved drug product, a drug manufacturer must file an ANDA that shows that the generic version is "therapeutically equivalent," or behaves almost the same when taken by a patient, to the branded drug product and, therefore, is substitutable.

For all pharmaceuticals sold in the U.S., the FDA also regulates sales and marketing to ensure that drug product claims made by manufacturers are neither false or misleading. Manufacturers are required to file copies of all product-specific promotional materials to the FDA's Office of Prescription Drug Promotion prior to their first use. In general, such advertising does not require FDA prior approval. Failure to implement a robust internal company review process and comply with FDA regulations regarding advertising and promotion increases the risk of enforcement action by either the FDA or the U.S. Department of Justice ("DOJ").

For both NDAs and ANDAs, the manufacture, marketing and selling of certain drug products may be limited by quota grants for controlled substances by the DEA. Refer to "Drug Enforcement Administration" within this Item 1. Business for further information.

NDA Process. The path leading to FDA approval of a NDA for a new chemical entity begins when the drug product is merely a chemical formulation in the laboratory. In general, the process involves the following steps:

- Completion of formulation and laboratory testing in accordance with GLP that fully characterizes the drug product from a pre-clinical perspective and provides preliminary evidence that the drug product is safe to test in human beings;
- Filing with the FDA an Investigational New Drug Application that will permit the conduct of clinical trials (testing in human beings under adequate and well-controlled conditions);
- Designing and conducting clinical trials to show the safety and efficacy of the drug product in accordance with GCP;
- Submitting the NDA for FDA review, which provides a complete characterization of the drug product;
- Satisfactory completion of FDA pre-approval inspections regarding the conduct of the clinical trials and the manufacturing processes at the designated facility in accordance with cGMP;
- If applicable, satisfactory completion of an FDA Advisory Committee meeting in which the FDA requests help from outside experts in evaluating the NDA;
- Final FDA approval of the full prescribing information, labeling and packaging of the drug product; and
- Ongoing monitoring and reporting of adverse events related to the drug product, implementation of a REMS program, if applicable, and conduct of any required Phase IV studies.

Clinical trials are typically conducted in four sequential phases, although they may overlap. The four phases are as follows:

- Phase I trials are typically small (less than 100 healthy volunteers) and are designed to determine the toxicity and maximum safe dose of the drug product.
- Phase II trials usually involve 100 to 300 participants and are designed to determine whether the drug product produces any clinically significant effects in patients with the intended disease or condition. If the results of these trials show promise, then a larger Phase III trial may be conducted.
- Phase III trials are often multi-institution studies that involve a large number of participants and are designed to show efficacy. Phase III (and some Phase II) trials are designed to be pivotal, or confirmatory trials. The goal of a pivotal trial is to establish the safety and efficacy of a drug product by eliminating biases and increasing statistical power.
- In some cases, the FDA requires Phase IV trials, which are usually performed after the NDA has been approved. Such **post-marketing surveillance** is intended to obtain more information about the risks of harm, benefits and optimal use of the drug product by observing the results of the drug product in a large number of patients.

A drug manufacturer may conduct clinical trials either in the U.S. or outside the U.S., but in all cases must comply with GCP, which includes (a) a legally effective informed consent process when enrolling participants; (b) an independent review by an Institutional Review Board to minimize and manage the risks of harm to participants; and (c) ongoing monitoring and reporting of adverse events related to the drug product.

In addition, a drug manufacturer may decide to conduct a clinical trial of a drug product on pediatric patients in order to obtain a form of marketing exclusivity as permitted under the Best Pharmaceuticals for Children Act ("BPCA"). Alternatively, the FDA may require a drug manufacturer, using its authority under the Pediatric Research Equity Act, to conduct a pediatric clinical trial. The goal of conducting pediatric clinical trials is to gather data on how drug products should best be administered to this patient population.

The path leading to FDA approval of a NDA for a drug product that has significant differences from an already approved one is somewhat shorter. The FDA requires a drug manufacturer to submit data from either already published reports or newly conducted studies that show the safety and efficacy of those differences. Significant differences include different dosage strengths or route of administration.

Under the U.S. Prescription Drug User Fee Act, the FDA has the authority to collect fees from drug manufacturers who submit NDAs for review and approval. These user fees help the FDA fund the drug approval process. For fiscal 2018, the user fee rate has been set at \$2,421,500 for a 505(b)(1) NDA and \$1,210,740 for a NDA not requiring a complete clinical data package, generally a 505(b)(2) NDA. We expense these fees as they are incurred. The average review time for a NDA is approximately six months for priority review and ten months for standard review.

ANDA Process. The path leading to FDA approval of an ANDA is much different from that of a NDA. By statute, the FDA waives the requirement for a drug manufacturer to complete pre-clinical studies and clinical trials and instead focuses on data from bioequivalence studies. Bioequivalence studies generally involve comparing the absorption rate and concentration levels of a generic drug in the human body to that of the branded drug or Reference Listed Drug ("RLD"). In the event that the generic drug behaves in the same manner in the human body as the RLD, the two drug products are considered bioequivalent. The FDA considers a generic drug therapeutically equivalent, and therefore substitutable, if it also contains the same active ingredients, dosage form, route of administration and strength.

In 2010, the U.S. Congress passed into law the Generic Drug User Fee Act to address the FDA's backlog, which at the time was over 2,000 ANDAs. This legislation granted the FDA authority to collect, for the first time, user fees from generic drug manufacturers who submit ANDAs for review and approval, and the fees collected will help the FDA fund the drug approval process. Under the Generic Drug User Fee Amendments of 2017, the fiscal 2018 user fee rate is set at \$171,820 for an ANDA and the prior approval supplement to an ANDA fee was removed. These fees are expensed as incurred. The FDA has set goal dates by fiscal year for ANDA submissions to improve the average review time. Fiscal 2018 has a target of approving 90% of ANDA submissions within 10 months of submission.

Aside from the backlog described above, the timing of FDA approval of ANDAs depends on other factors, including whether an ANDA holder has challenged any listed patents to the RLD and whether the RLD is entitled to one or more periods of marketing exclusivity under the FDCA (such as pediatric exclusivity under the BPCA). In general, the FDA will not approve (but will continue to review) an ANDA in which the RLD holder has sued, within 45 days of receiving notice of the ANDA filing, the ANDA holder for patent infringement until either the litigation has been resolved or 30 months has elapsed, whichever is later.

Patent and Non-Patent Exclusivity Periods. A sponsor of a NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in the Orange Book. Any person that files a Section 505(b)(2) NDA, the type of NDA that relies upon the data in the application for which the patents are listed, or an ANDA to secure approval of a generic version of a previous drug, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless the generic applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder of the NDA for the

Item 1A. Risk Factors.

You should carefully consider the risks described below in addition to all other information provided to you in this Annual Report on Form 10-K. Our competitive position, business, financial condition, results of operations and cash flows could be affected by the factors set forth below, any one of which could cause our actual results to vary materially from recent results or from our anticipated future results. The risks and uncertainties described below are those that we currently believe may materially affect our company.

Risks Related to Our Business

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. The following discussion highlights some of these risks and others are discussed elsewhere in this Annual Report on Form 10-K. These and other risks could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Extensive laws and regulations govern the industry in which we operate and changes to those laws and regulations may materially adversely affect us.

The development, manufacture, marketing, sale, promotion, and distribution of our products are subject to comprehensive government regulations that govern and influence the development, testing, manufacturing, processing, packaging, holding, record keeping, safety, efficacy, approval, advertising, promotion, sale, distribution and import/export of our products.

Under these laws and regulations, we are subject to periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the DEA and similar authorities within and outside the U.S., which conduct periodic inspections to confirm that we are in compliance with all applicable requirements. We are also required to track and report adverse events and product quality problems associated with our products to the FDA and other regulatory authorities. Failure to comply with the requirements of FDA or other regulatory authorities, including a failed inspection or a failure in our adverse event reporting system, or any other unexpected or serious health or safety concerns associated with our products, including opioid pain products and H.P. Acthar Gel, could result in adverse inspection reports, warning letters, product recalls or seizures, product liability claims, labeling changes, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could cause a loss of customer confidence in our products, which could adversely affect our sales, or otherwise have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. In addition, the requirements of regulatory authorities, including interpretative guidance, are subject to change and compliance with additional or changing requirements or interpretative guidance may subject the company to further review, result in product delays or otherwise increase our costs, and thus have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Furthermore, the FDA and other foreign regulatory authorities approve drugs and medical devices for the treatment of specific indications, and products may only be promoted or marketed for the indications for which they have been approved. However, in the U.S. the FDA does not attempt to regulate physicians' use of approved products, and physicians are free to prescribe most approved products for purposes outside the indication for which they have been approved. This practice is sometimes referred to as "off-label" use. While physicians are free to prescribe approved products for unapproved uses, it is unlawful for drug and device manufacturers to market or promote a product for an unapproved use. The laws and regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other governmental agencies. Promotion of a product for unapproved use is prohibited; however, certain activities that we and others in the pharmaceutical industry engage in are permitted by the FDA. We have compliance programs in place, including policies, training and various forms of monitoring, designed to address these risks. Nonetheless, these programs and policies may not always protect us from conduct by individual employees that violate these laws. If the FDA or any other governmental agency initiates an enforcement action against us and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses in connection with past or future activities, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions could have an adverse effect on our business, financial condition, results of operations and cash flows.

If our business development activities are unsuccessful, it may adversely affect us.

Part of our business strategy includes evaluating potential business development opportunities to grow the business through merger, acquisition, licensing agreements or other strategic transactions. The process to evaluate potential opportunities may be complex, time-consuming and expensive. Once a potential opportunity is identified, we may not be able to conclude negotiations of a

We may be unable to successfully develop, commercialize or launch new products or expand commercial opportunities for existing products or adapt to a changing technology and, as a result, our business may suffer.

Our future results of operations will depend, to a significant extent, upon our ability to successfully develop, commercialize and launch new products or expand commercial opportunities for existing products in a timely manner. There are numerous difficulties in developing, commercializing and launching new products or expanding commercial opportunities for existing products, including:

- developing, testing and manufacturing products in compliance with regulatory and quality standards in a timely manner;
- our ability to successfully engage with the FDA or other regulatory authorities as part of the approval process and to receive requisite regulatory approvals for such products in a timely manner, or at all;
- the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients;
- developing, commercializing and launching a new product is time-consuming, costly and subject to numerous factors, including legal actions brought by our competitors, that may delay or prevent the development, commercialization and/or launch of new products;
- unanticipated costs;
- payment of prescription drug user fees to the FDA to defray the costs of review and approval of marketing applications for branded and generic drugs;
- experiencing delays as a result of limited resources at the FDA or other regulatory authorities;
- changing review and approval policies and standards at the FDA or other regulatory authorities;
- potential delays in the commercialization of generic products by up to 30 months resulting from the listing of patents with the FDA;
- effective execution of the product launches in a manner that is consistent with expected timelines and anticipated costs; and
- identifying appropriate partners for distribution of our products, including for any future over-the-counter commercialization opportunities, and negotiating contractual arrangements in a timely manner with commercially reasonable terms.

As a result of these and other difficulties, products currently in development by us may or may not receive timely regulatory approvals, or approvals at all. This risk is heightened with respect to the development of proprietary branded products due to the uncertainties, higher costs and length of time associated with R&D of such products and the inherent unproven market acceptance of such products. Moreover, the FDA regulates the facilities, processes and procedures used to manufacture and market pharmaceutical products in the U.S. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with cGMP regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects both our facilities and procedures to ensure compliance with regulatory standards. The FDA may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. In the event an approved manufacturing facility for a particular drug is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

Furthermore, the market perception and reputation of our products are important to our business and the continued acceptance of our products. Any negative press reports or other commentary about our products, whether accurate or not, could have a material adverse effect on our business, reputation, financial condition, cash flows or results of operation or could cause the market value of our common shares and/or debt securities to decline.

With respect to generic products for which we are the first developer to have its application accepted for filing by the FDA, and which filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (known as a "Paragraph IV certification"), our ability to obtain and realize the full benefits of 180-days of market exclusivity is dependent upon a number of factors, including, being the first to file, the status of any litigation that might be brought against us as a result of our filing or our not meeting regulatory, manufacturing or quality requirements or standards. If any of our products are not approved timely, or if we are unable to obtain and realize the full benefits of the respective market exclusivity period for our products, or if our products cannot be successfully manufactured or commercialized timely, our results of operations could be materially adversely affected. In addition, we cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products. Finally, once developed and approved, new products may fail to achieve commercial acceptance due to the price of the product, third-party reimbursement of the product and the effectiveness of sales and marketing efforts to support the product.

Our product concentration may materially adversely affect our business.

We sell a wide variety of products including specialty branded and specialty generic pharmaceuticals, as well as API. However, a small number of relatively significant products, most notably H.P. Acthar Gel and to a lesser extent, Inomax, Ofirmev and Therakos, represent a significant percentage of our net sales. Our ability to maintain and increase net sales from these products depends on several factors, including:

- our ability to increase market demand for products through our own marketing and support of our sales force;
- our ability to implement and maintain pricing and continue to maintain or increase market demand for these products;
- our ability to achieve hospital and other third-party payer formulary acceptance, and maintain reimbursement levels by third-party payers;
- our ability to maintain confidentiality of the proprietary know-how and trade secrets relating to H.P. Acthar Gel;
- our ability to maintain and defend the patent protection and regulatory exclusivity of Ofirmev and Inomax;
- our ability to continue to procure raw materials or finished goods, as applicable, for H.P. Acthar Gel, Ofirmev, Inomax and Therakos from internal and third-party manufacturers in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- our ability to maintain fees and discounts payable to the wholesalers and distributors and group purchasing organizations, at commercially reasonable levels;
- whether the DOJ or third parties seek to challenge and are successful in challenging patents or patent-related settlement agreements or our sales and marketing practices;
- warnings or limitations that may be required to be added to FDA-approved labeling; and
- the occurrence of adverse side effects related to or emergence of new information related to the therapeutic efficacy of these products, and any resulting product liability claims or product recalls.

Moreover, net sales of H.P. Acthar Gel may also be materially impacted by the decrease in the relatively small number of prescriptions written for H.P. Acthar Gel as compared to other products in our portfolio, given H.P. Acthar Gel's use in treating rare diseases. Any disruption in our ability to generate net sales from H.P. Acthar Gel could have an adverse impact on our business, financial condition, results of operations and cash flows.

Cost-containment efforts of our customers, purchasing groups, third-party payers and governmental organizations could materially adversely affect our business.

In an effort to reduce cost, many existing and potential customers for our products within the U.S. have become members of GPOs and integrated delivery networks ("IDNs"). GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple manufacturers with the intention of driving down pricing. Due to the highly competitive nature of the GPO and IDN contracting processes, there is no assurance that we will be able to obtain or maintain contracts with major GPOs and IDNs across our product portfolio. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our profitability. While having a contract with a GPO or IDN for a given product can facilitate sales to members of that GPO or IDN, having a contract is no assurance that sales volume of those products will be maintained. GPOs and IDNs increasingly are awarding contracts to multiple suppliers for the same product category. Even when we are the sole contracted supplier of a GPO or IDN for a certain product, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days prior notice. Accordingly, our net sales and results of operations may be negatively affected by the loss of a contract with a GPO or IDN. In addition, although we have contracts with many major GPOs and IDNs, the members of such groups may choose to purchase from our competitors, which could result in a decline in our net sales. Distributors of our products are also forming strategic alliances and negotiating terms of sale more aggressively in an effort to increase their profitability. Failure to negotiate distribution arrangements having advantageous pricing and other terms of sale could cause us to lose market share to our competitors or result in lower pricing on volume we retain, both of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. Outside the U.S., we have experienced pricing pressure due to the concentration of purchasing power in centralized governmental healthcare authorities and increased efforts by such authorities to lower healthcare costs. We frequently are required to engage in competitive bidding for the sale of our products to governmental purchasing agents. Our failure to maintain volume and pricing with historical or anticipated levels could materially adversely affect our business, financial condition, results of operations and cash flows.

result in a decline in our sales volume. For further discussion on the competitive nature of our business, as well as the intellectual property rights and market exclusivity that play a key role in our business, refer to Item 1. Business included within this Annual Report on Form 10-K. Our failure to compete effectively could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We may incur product liability losses and other litigation liability.

We are or may be involved in various legal proceedings and certain government inquiries and investigations, including with respect to, but not limited to, patent infringement, product liability, personal injury, antitrust matters, securities class action lawsuits, breach of contract, Medicare and Medicaid reimbursement claims, opioid related matters, promotional practices and compliance with laws relating to the manufacture and sale of controlled substances. For example, we, along with other opioid manufacturers and, often, distributors, have been named in lawsuits related to the manufacturing, distribution, marketing and promotion of opioids. In addition, we have also received various subpoenas and requests for information related to the distribution, marketing and sale of our opioid products. Such proceedings, inquiries and investigations may involve claims for, or the possibility of, fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties, changes in business practices and exclusion from participation in various government healthcare-related programs. Such litigation and related matters are described in Note 19 of the Notes to Consolidated Financial Statements included within Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K. If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

With respect to product liability and clinical trial risks, in the ordinary course of business we are subject to liability claims and lawsuits, including potential class actions, alleging that our marketed products or products in development have caused, or could cause, serious adverse events or other injury. Any such claim brought against us, with or without merit, could be costly to defend and could result in an increase in our insurance premiums. We retain liability for \$10.0 million per claim of the first \$40.0 million of a loss in our primary liability policies and purchase an additional \$135.0 million using a combination of umbrella/excess liability policies with respect to any such claims. We believe this coverage level is adequate to address our current risk exposure related to product liability claims and lawsuits. However, some claims brought against us might not be covered by our insurance policies. Moreover, where the claim is covered by our insurance, if our insurance coverage is inadequate, we would have to pay the amount of any settlement or judgment that is in excess of our policy limits. We may not be able to obtain insurance on terms acceptable to us or at all since insurance varies in cost and can be difficult to obtain. Our failure to maintain adequate insurance coverage or successfully defend against product liability claims could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The healthcare industry has been under increasing scrutiny from governments, legislative bodies and enforcement agencies related to the promotion of products and related activities, and changes to, or non-compliance with, relevant policies, laws, regulations or government guidance may result in actions that could adversely affect our business.

In the U.S. over the past several years, a significant number of pharmaceutical and biotechnology companies have been subject to inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales, marketing and pricing practices, including the DOJ and various other agencies including the Office of the Inspector General within the Department of Health and Human Services (OIG), the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, data and patient privacy laws, export and import laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. The DOJ and the U.S. Securities and Exchange Commission ("SEC") have also increased their focus on the enforcement of the FCPA, particularly as it relates to the conduct of pharmaceutical companies.

Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a "qui tam" suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If the government declines to intervene and prosecute the case, the individual may pursue the case alone. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses in connection with past or future activities, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as the possible exclusion from federal healthcare programs including Medicare and Medicaid, consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny

- *Ofirmev* is a proprietary intravenous formulation of acetaminophen indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever. This product is marketed to hospitals and ambulatory surgical centers and provides us with an expanded presence in these channels. *Ofirmev* is protected by two Orange Book-listed patents that expire in August 2017 and June 2021 and we have the potential to obtain an additional six months of exclusivity for each patent if the FDA grants pediatric exclusivity. Settlement agreements have been reached in association with certain challenges to these patents, which allow for generic competitors to *Ofirmev* in December 2020, or earlier under certain circumstances.
- *Xartemis XR* is the first and only extended-release oral combination of oxycodone and acetaminophen. *Xartemis XR* is approved for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. In February 2014, we were granted a patent from the USPTO, which contains composition claims directed to unique design, formulation, pharmacokinetic and release characteristics of *Xartemis XR*. *Xartemis XR* received FDA approval and was launched in March 2014.
- *Exalgo*, which was acquired in June 2009, is the only branded long-acting, once-daily form of hydromorphone in the U.S. market. In August 2012, the FDA approved a 32 mg tablet of *Exalgo*, which further expanded the patient population that *Exalgo* can effectively treat with a single daily dose. The 8 mg, 12 mg and 16 mg dosages of *Exalgo* were approved by the FDA in March 2010 for the treatment of chronic pain in opioid-tolerant patients requiring continuous around-the-clock opioid analgesia for an extended amount of time, and have shown significant prescription growth since launch in April 2010. Our exclusivity period for *Exalgo* has expired and generic competition entered the market beginning in May 2014. In anticipation of this loss of exclusivity, we launched a generic form of *Exalgo* in May 2014. We expect sales of *Exalgo*, across both the branded and authorized generic product, to decrease in fiscal 2015 compared with net sales in fiscal 2014.

Generics and API

We market our API products to other pharmaceutical companies around the world, many of which are competitors of our Brands and Generics businesses. Additionally, we use our API for internal manufacturing of our finished dosage products. We are among the largest manufacturers of bulk acetaminophen in the world and the only producer of acetaminophen outside of Asia. We manufacture controlled substances under DEA quota restrictions and in calendar 2013 we believe we received approximately 26% of the total DEA quota provided to the U.S. market for the controlled substances we manufacture. We believe that our strong market position in the API business and allocation of opioid raw materials from the DEA is a competitive advantage for our API business and, in turn, for our Generics and Brands businesses. The strategy for our API business is based on manufacturing large volumes of high-quality product and customized product offerings, responsive technical services and timely delivery to our customers.

We believe our Generics and API businesses represent the broadest product line of opioid and other controlled substances (primarily DEA Schedules II and III) currently available from a single manufacturer. Our Generics and API businesses have a strong position in the controlled substance generics market with products, including hydrocodone, hydrocodone-containing tablets, oxycodone and oxycodone-containing tablets, all of which are significant products in the overall pain products industry, as well as other controlled substance products. Historically, our primary competition has been other U.S. participants due to importation restrictions on controlled substance API and finished products. Our commitment to investment in our R&D infrastructure and capabilities has resulted in a pipeline of generic controlled substances, many of which are long-acting or hard to formulate products, which are under development or pending approval by the FDA.

We market our generic products principally through drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, food store chains with pharmacies, pharmaceutical benefit managers that have mail order pharmacies and hospital buying groups.

The following is a list of significant products and product families in our Generics and API product portfolio:

- hydrocodone (API) and hydrocodone-containing tablets;
- oxycodone (API) and oxycodone-containing tablets;
- methylphenidate HCl extended-release tablets USP (CII) ("Methylphenidate ER") and;
- other controlled substances, including acetaminophen (API) products.